U.S. Patent and Trademark Office: U.S. DEPARTMENT OF GOMMERGE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/888,311 INFORMATION DISCLOSURE 6/22/01 Filing Date STATEMENT BY APPLICANT Weers et al. **First Named Inventor** 1617 Art Unit (use as many sheets as necessary) K. Stiller Examiner Name Attorney Docket Number 0103.00 of Sheet

<u> </u>	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		US-					
		US-					
		US-					
	<u> </u>	US-					
		US-		•			
		US-					
		US-					
		US-					
		US-					
	•	US-					
		US-					
		US-					
_		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,					
		Country Code3 -Number4 -Kind Code5 (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Т6				
	gk	wo 9916419	4/8/1999							
	gl	wo 0113892	3/1/2001							
·										
			<u></u>							
			<u> </u>							
		•		1						

	····		T
Examiner		Date	
Signature		Considered	
			<u>. </u>

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 6651-0931

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no bersons are required to respond to a collection of information unless it contains a valid OMB control number.

control number.

Complete if Known Substitute for form 1449B/PTO 09/888.311 **Application Number** INFORMATION DISCLOSURE 6/22/01 Filing Date STATEMENT BY APPLICANT Jeffry Weers et al First Named Inventor 1617 Group Art Unit K. Stiller (use as many sheets as necessary) Examiner Name Attorney Docket Number of Sheet 0103.00

	ſ	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	<u> </u>
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	-
	1	ABDELLAZIZ BEN-JEBRIA ET AL., "Large Porous Particles for Sustained Protection from Carbachol-Induced Brnchoconstriction in Guinea Pigs," Pharm Res, Vol. 16 (No. 4), p. 555-561,	
	2	ZARIF ET AL., "Amphotericin B Cochleates as a Novel Oral Delivery System," International Symposium, p. 964-965,	
	3	HAUSER ET AL., "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes," Biochem., p. 34-41,	
	,		
			-
			Ŀ

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

COPY OF PAPERS
ORIGINALLY FILE

	•
FORM PTO-1449	U.S. DEPARTMENT OF COM
	PATENT AND TRADEMARK

	•	
IT OF COMMERCE ADEMARK OFFICE	ATTY. DOCKET NO.	APPLICATION NO.

INFORMATION	DISCLOSURE	STATEMENT
В	Y APPLICANT	

	i
0103.00	09/888,311

BY APPLICANT

APPLICANT Weers et al.

FILING DATE 6/22/2001

GROUP

1.617

EATER LA CO	1			U.S. PATENT DOCUMENTS			
XAMINER		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
NITIAL							
()	1.	5,308,620	5/1994	Yen			0
0,	2.	5,562,608	10/1996	Sekins et al.	ſ		2007
	3.	5,616,311	4/1997	Yen			009
	4.	5,673,686	10/1997	Villax et al.			5 H
	5.	5,676,929	10/1997	Akehurst et al.		(
	6.	5,829,435	11/1998	Rubsamen et al.		/ Ц	
	7.	5,855,913	1/1999	Hanes et al.		Ω	3
	8.	5,874,064	2/1999	Edwards et al.			-
	9.	6,019,968	2/2000	Platz et al.			
	10.	6,041,777	3/2000	Faithful et al.			
4	11.	6,048,546	4/2000	Sasaki et al.	_		

V			F	DREIGN PATENT DOCUMENT	S			
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY		CLAS	SUBCLASS	TRANSLATION YES NO
~	12.	714998	1/2000	AU				
1	13.	0 274 431 A2 🖊	7/1988	EPO		1	N	
	14.	0 372 777 A2	6/1990	EPO				
	15.	0 611 567 A1	8/1994	EPO				
	16.	9 619 198	6/1996	wo				
	17.	9 736 574	10/1997	wo				
	18.	9 736 578 🖊	10/1997	wo				
	19.	. 9 744 012 /	11/1997	wo				
	20.	9 916 419	4/1999	wo				
	21.	9 916 420	4/1999	wo				
	22.	9 916 421	4/1999	wo				
	23.	9 916 422	4/1999	wo				
	24.	0 000 176	1/2000	wo				
	25.	0 000 215	6/2000	wo		1		
A/	26.	0 113 892	3/2001	wo		_		

	
EXAMINER	DATE CONSIDERED 12/02

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

			COPY OF PAPER			SHEET	2 QE-3,
FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	ORIGINALLY FILE	APPLICATION NO.	E	02	0/290
INFORMATION (DISCLOSURE STATEMENT	0103.00		09/888,	31	5 2002	160
	APPLICANT	APPLICANT Weers et	al		CE	2 N	NTER
(USE SEVERAL	SHEETS IF NECESSARY)	FILING DATE 6/22/200	1	GROUP 161	7	2	HCE

AMINER ITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
N	27.	Dellamary et al. "Hollow Porous Particles in Metered Dose Inhalers" Pharm Research 17(2): 168-174 (2000).
	28.	Ahlneck et al. "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State" Int. J. of Pharmaceutics 62: 87-95 (1990).
	29.	Altenbach et al. "Ca²+ Binding to Phosphatidycholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for th Formation of a Ca²+ Complex with Two Phospholipid Molecules" Biochemistry 23: 3913-3920 (1984).
	30.	Babincova et al. "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposomes: Possible Implications fo Exocytosis" Physiol Res 48(4): 319-321 (1999).
	31.	Buckton et al. "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders" In J. of Pharmaceutics 123: 265-271 (1995).
	32.	Buldt et al. "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes" J. Mol. Biol. 134: 673-691 (1979).
	33.	Cevc, G. "Membrane Electrostatics" Biochim Biophys Acta 1031(3): 311-382 (1990)., in particular pp 330-338.
	34.	Duzgunes et al. "Studies on the Mechanism of Membrane Fusion. Role of Head-Group Composition in Calcium- and Magnesium-Induced Fusion of Mixed Phospholipid Vesicles" Biochim Biophys Acta 642: 182-195 (1981).
	35.	Ebara et al. "Interactions of Calcium Ions with Phospholipid Membranes" Langmuir 10: 2267-2271 (April, 1994).
	36.	Eisenberg et al. "Adsorption of Monovalent Cations to Bilayer Membranes Containing Negative Phospholipids" Blochemistry 18(23): 5213-5223 (1979).
	37.	Goldbach et al. "Spray-Drying of Liposomes for a Pulmonary Administration I. Chemical Stability of Phospholipids" Drug Develop Ind Pharm 19(19): 2611-2622 (1993).
	38.	Gordon et al. "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. I. Non-Crystalline Copolymers" J. Appl. Chem. 2: 493-500 (Sept., 1952).
	39.	Hancock et al. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems" J. of Pharmaceutical Sciences 86(1): 1-12 (Jan., 1997).
	40.	Hancock et al. "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solids" Pharm Research 11(4): 471-477 (1994).
	41.	Hauser et al. "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers" Biochim Biophys Acta 813: 343-346 (1985).
	42.	Hauser et al. "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" Biochemistry 23: 34-41 (1984).
	43.	Huster et al. "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction" Biophys J. 77(2): 879-887 (Aug., 1999).
	44.	Huster et al. "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" Biophys J. 78(6 3011-3018 (June, 2000).
	45.	Jacobson et al. "Phase Transitions and Phase Separations in Phospholipid Membranes Induced by Changes in Temperature, pH, and Concentration of Bivalent Cations" Biochemistry 14(1): 152-161 (1975).
	46.	Kwon et al. "Calcium Ion Adsorption on Phospholipid Bilayers- Theoretical Interpretation" J Jap Oil Chem Soc 43(1): 23-30 (1994).
7	47.	Lis et al. "Adsorption of Divalent Cations to a Variety of Phosphatidylcholine Bilayers" Biochemistry 20: 1771-1777 (1981).

EXAMINER		DATE CONSIDERED 12/02	
	TTATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORCED OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT	RMANCE WITH MPEP 609, DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND	D NOT

 $\overset{\text{i.i.}}{\Psi}$

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

0103.00

6/22/2001

ATTY, DOCKET NO.

*APPLICATION NO.

1617

09/888,311>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICANT

FILING DATE

Weers et al

GROUP

(USE SEVERAL SHEETS IF NECESSARY)

EXAMINER OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) INITIAL 48. Lis et al. "Binding of Divalent Cations to Dipalmitoylphosphatidylcholine Bilayers and Its Effect on Bilayer Interaction" Biochemistry 20: 1761-1770 (1981). Millqvist-Fureby et al. "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures" Int. J. Pharm. 191: 103-114 49. (1999).Millgvist-Fureby et al. "Spray-Drying of Trypsin - Surface Characterisation and Activity Preservation" Int. J. Pharm. 188: 243-50. 253 (1999). Parasassi et al. "Calcium-Induced Phase Separation in Phospholipid Bilayers. A Fluorescence Anisotropy" Cellular and 51. Molecul Bio 32(3): 261-266 (1986). 52. Reboiras, M.D. "Activity Coefficients of CaCl₂ and MgCl₂ in the Presence of Dipalmitoylphosphatidylcholine-Phosphatidylinositol Vesicles in Aqueous Media" Bioelectrochemistry and Bioenergetics 39: 101-108 (1996). Royall et al. "Characterisation of Moisture Uptake Effects on the Glass Transitional Behaviour of an Amorphous Drug Using **53**. Modulated Temperature DSC" Int. J. Pharm. 192: 39-46 (1999). Satoh, Koichi. "Determintation of Binding Constants of Ca2+, Na+, and Cl- tons to Liposomal Membranes of 54. Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis" Biochim Biophys Acta 1239: 239-248 (1995). Seddon, J.M. "Structure of the Inverted Hexagonal (Hill) Phase, and Non-Lamellar Phase Transitions of Lipids" Blochim **55**. Biophys Acta 1031: 1-69 (1990)., in particular p. 43-44 and 49-50. 1. Joachim Seelig, Handb. Met. -Ligand Interact. Biol. Fluids: Bioinorg. Chem. § Metal Ion Interactions with Lipids: 698-706 56. (1995). Shah et al. "The Ionic Structure of Sphingomyelin Monolayers" Blochim Biophys Acta 135: 184-187 (1967). 57. 58. Shavnin et al. "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" Biochim Biophys Acta 946: 405-416 (1988). Simha et al. "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers" J. Chem. 59. Physics 37(5): 1003-1007 (Sept., 1962). Sugisaki et al. "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice" Bulletin of the **60**. Chemical Society of Japan 41: 2591-2599 (Nov., 1968). Tatulian, S.A. "Binding of Alkaline-Earth Metal Cations and Some Anions to Phosphatidylcholine Liposomes" Eur. J. Biochem. 61. **170:** 413–420 (1987). Tatulian, S.A. "Evalutation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration 62. Dependence of Surface Potential J. Colloid Interface Science 175: 131-137 (1995). 63. Verstraeten et al. "Effects of Al(3+) and Related Metals on Membrane Phase State and Hydration: Correlation with Lipid Oxidation" Arch Biochem Biophys 375(2): 340-346 (March 15, 2000). Whipps et al. "Growth of Calcium Monohydrate at Phospholipid Langmuir Monolayers" J Cryst Growth 192: 243-249 (1998). 64. 65. Yamaguchi et al. "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" Colloids and Surfaces B:

S:\DOCS\(\)LD\JLD-1997.DOC\021302

Biointerfaces 5: 49-55 (1995).

EXAMINER	DATE CONSIDERED	12/02/
		10/100

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

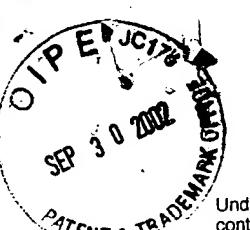
FOR	M PTO-1449	U.S. DEPARTMEN PATENT AND TR	IT OF COMMERC	l l	NO.	APPLIC	ATION NO.		
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			0103.0	00	09	/888,3	11	
				APPLICANT Weers	et al.				
P	HUSE-SEVER	AL SHEETS IF NECES	SARY)	FILING DATE / 2	2001	GROUP	1617		
70	1 B. MOT								PAPERS LY FILED
MA				U.S. PATENT DOC	UMENTS				
EXAMINER INITIAL	NT 2 77-60	CUMENT NUMBER	DATE		NAME	CLASS	SUBCLASS		G DATE (OPRIATE)
	1.	5.994,318	11/30/99 Go	ould-Fogerite et al.					00/2900
1									600/
V									, ~
								⇔	
						ļ . <u></u>			- HOH
		<u> </u>			· •				
						<u></u>		<u> </u>	
·			F	OREIGN PATENT DO	DCUMENTS				
EXAMINER	DOG	CUMENT NUMBER	DATE	C	OUNTRY	CLASS	SUBCLASS	TRANS	LATION
INITIAL								YES	NO
1	2.	WO 98/31346	07/23/98 PC	CT	· · · · · · · · · · · · · · · · · · ·	<u> </u>			
-									
EXAMINER		ОТ	HER DOCUMENT	S (INCLUDING AUTH	OR, TITLE, DATE, PERTINENT	PAGES,	ETC.)		
INITIAL	3. Zarif, et a	al. (1999) Amphotericin	B cochleates as a	novel oral delivery sys	tem for the treatment of fungal in	····		the Internation	onai
	Symposi	um on Controlled Relea	se bloacuve mater	iais. pp. 904-905, XP-(VUZ 1453ZZ			~	
<u> </u>		(507)		4.4. 1.00.00.00.00.00.00.00.00					
	Courtesy	copy of PCT Internation	nai Search Report	aated 02/28/02 in 3 pa	iges.				
<u> </u>									
S:\DOCS\JL	D\JLD-2082.1	DOC\031302							

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

DATE CONSIDERED

EXAMINER

12/02





Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARIMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless in the process of the control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/888.311 **INFORMATION DISCLOSURE** 06/22/2001 Filing Date Jeffry Weers STATEMENT BY APPLICANT **First Named Inventor** 1617 Art Unit (use as many sheets as necessary) E. Webman **Examiner Name** Attorney Docket Number 0103.00 of Sheet

			U.S. PATI	ENT DOCUMENTS	
Examine	Cite No. 1	Document Number Number - Kind Code 2 (if known)		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1	1	US-4161516	07/17/1979	Bell	
[/ 1	2	US-5855913	1/5/1999	Hanes et al.	
V	3	US-5673686	10/7/1997	Villax et al.	
	4	US-4995385	2/26/1991	Valentini et al.	
	5	US- 4358442	11/9/1982	Wirtz-Peitz et al.	
	6	US- 4404228	9/13/1983	Cloosterman et al.	
4	7	US- 5747001	5/5/1998_	Widemann et al.	
d	8	US-5994318	11/30/1999	Gould Fogerite et al.	<u></u>
1		US-			
U		US-			
		US-			
		US-			
		US-	· · · · · · · · · · · · · · · · · · ·		
· ·		US-			
		US-			
		US			
		US-			
		US-			
		US-			
_		US-			

			FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1		Foreign Patent Document 3 -Number - Kind Code (if known)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
9	9	WO	01/95874	12/20/2001	Adv. Inhalation		
01	10	AU	714998	1/18/1997	Lipesome Company B		
	11	wo	91/16444	10/31/1991	Yagi Antenna Li	rosomt Co	<u> </u>
	12	JP	03038592	2/19/1991	Yagi Antenna		
	13	UK	206569	7/1/1991	Nattermann & CIE		ļ
lacksquare							
- <u> </u>	1	<u> </u>					\vdash
<u> </u>	1						

Examiner Signature	Date Considered	12/	62	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.



U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information under the paperwork Reduction Reduction Act of 1995, no persons are required to respond to a collection of information under the paperwork Reduction R

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known					
Application Number	09/888.311				
Filing Date	06/22/2001				
First Named Inventor	Jeffry Weers				
Art Unit	1617				
Examiner Name	E. Webman				
Attorney Docket Number	0103.00				

		U.S. PATE	NT DOCUMENTS	
Examiner Initials*	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US-			
	US-			
	US-			
_	US-			
	 US-			
-	US-			
	US-			

		FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т6
4	wo	99/16419 —	4/8/1999	Alliance		
	wo	99/38493	8/5/1999	RTP Pharma		
	wo	99/66903 🖊	12/29/1999	Advanced Inhalation		
	wo	00/10541	3/2/2000	Advanced Inhalation		
	wo	00/72904	12/7/2000	Inhale		
	wo	00/21594	4/20/2000	Inhale		
	wo	01/00263	1/4/2001	Inhale		
-						
						Ī

	_		
Examiner		Date	12 / 12
Signature		Considered	16/00

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

(use as many sheets as necessary)

of

Complete if Known 09/888.311 **Application Number** 06/22/2001 Filing Date **First Named Inventor** Jeffry Weers <u>1617</u> Group Art Unit E. Webman **Examiner Name** Attorney Docket Number 0103.00

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T;
1	14	CHRIS CUNBAR ET AL., "Dispersion and Characterization of Pharmaceutical Dry Powder Aerosols," KONA, 1998	
<i>U</i>	15	BORGSTROM ET AL., "Lung Deposition of Budesonide Inhaled via Turbuhaler," Eur. Respir. J., p. 69-73, 1994	
	16	C. ROTH ET AL., "Production of Hollow Spheres," Pargamon Press, Vol. 19 (No. 7), p. 939-942, 1988	
	!		
			+
			+
	:		

		· •
Examiner	Date	12/12
Signature	Considered	16/00

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

JUN 0 3 2002

Substitute for form 1449A/PTO

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of Sheet

Co	mplete if Known	REA	EIVED
Application Number	09/888.311		KCINED
Filing Date	6/22/01		
First Named Inventor	Jeffry Weers et al.	0014	0 4 2002
Art Unit	1617	TECHOEN	CD / 6
Examiner Name	K. Stiller	I LOTT CETY	ER 1600/2900
Attorney Docket Number	0103.00		330/2000

			U.S. PATI	ENT DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1	aa	US-4571334	02/18/1986	Yoshisa et al	
1	ab	US-4765987		Bonte et al.	
1/ [ac	US- 5032585		Lichtenberger	
	ad	US- 5262405		Girod-Vaquez et al.	
	ae	US- 5299566	04/05/1994	Davis et al.	
	af	US- 5451569	09/19/1995		
	ag	US- 5527521	06/18/1996		
	ah	US- 5542935	08/06/1996	Unger et al.	
	ai	US- 5569448	10/19/1996	Wong et al.	
	aj	US- 5648095	07/15/1997	Illum et al.	
	ak	US- 5659297	08/12/1997	Bernstein et al.	
	al	US- 5667808	09/16/1997	Johnson et al.	
	am	US- 5698537	12/16/1997	Pruss	
	an	US- 5776496	07/07/1998	Violante et al.	
	ao	US- 5853698	12/29/1998	Straub et al.	
	ар	US- 5853752		Unger et al.	
	aq	US- 5853763	12/19/1998		
	ar	US- 5925334	07/20/1999		
	as	US- 5955143	09/21/1999		
(γ^{-})	at	US- 5985309	11/16/1999	Edwards et al.	

		FORE	IGN PATENT D	OCUMENTS		
Examiner		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.1	Country Code3 -Number4 -Kind Code5 (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	Te
9	es	WO 9626746		9/6/1996		
	ET	WO 9808519		3/5/1998		
	EU	WO 9805302 -		2/12/1998		
	EV	WO 9801161 -		1/15/1998		
	EW	WO 9744013 -		11/27/1997		
	EX	WO 9744012		11/27/1997		
	EY	WO 9817257 -		4/30/1998		
	EZ	WO 9736578		10/9/1997		
٨	FA	WO 9736574		10/9/1997		
Y	FB	WO 9735562		10/2/1997	<u> </u>	

Examiner Signature	Date	12/02-
Olgitature	Considered	12/0

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

0 4 2002

U.S. Patent and Trademark Onice. U.S. Der Attimice. U.S. Der Attimice.

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/888.311 INFORMATION DISCLOSURE 6/22/01 Filing Date STATEMENT BY APPLICANT **First Named Inventor** Jeffry Weers et al. 1617 Art Unit (use as many sheets as necessary) K. Stiller **Examiner Name** Attorney Docket Number 0103.00 2 9 of Sheet

<u>-</u>			U.S. PATI	ENT DOCUMENTS	
Examiner nitials*		Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
4	au	US-6017310	01/25/2000	Johnson et al.	Tiguico Appeai
/	av	US-6051259	04/18/2000	Johnson et al.	
	aw	US-6068600	05/30/2000	Johnson et al.	
	ax	US-6068600	07/11/2000	Johnson et al.	
	ay	US-6113948	09/05/2000	Heath et al.	
	az	US-6129934	10/10/2000	Egan et al.	
	ba	US-6165597		Tracy et al.	
	bb	US-4397799	08/09/1983	Edgren et al.	
	bc	US-5855913	01/05/1999	Hanes et al.	
	bd	US-5308620	05/03/1994	Yen	
	be	US-5616311	04/01/1997	Yen	
	bf	US-5874064	04/02/1999	Edwards et al.	
	bg	US-5306483	04/04/1994	Mautone	
	bh	US-5690954	04/11/1997	Illum	
	bi	US-5260306	04/11/1993	Boardman et al.	
1	bj	US-5707644	04/01/1998	Illum	
<u> </u>	bk	US-5225183	04/07/1993		
	bl	US-5145684		Liversidge et al.	
	bm	US-5658549	04/08/1997	Akehurst et al.	
1/	bn	US-5605673	02/25/1997	Schutt et al.	

			FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1		umber ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т
0	FC	WO	9619968	7/4/1996			
0	FD	wo	9619198	6/27/1996			
	FE	WO	9619197.	6/27/1996			
	FF	WO	9618388	6/20/1996		· · · · · · · · · · · · · · · · · · ·	
	FG	WO	9615814 -	5/30/1996			
	FH	wo	96109814	4/4/1996			
	FI	wo	9523613	9/8/1995			
	FJ	wo	9531964 🖊	11/30/1995			
	FK	wo	9531182	11/23/1995			
	FL	wo	9527476	10/19/1995			

Examiner	^ ^ -	Date	/
Signature		Considered	12/02

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 09/888.311 **Application Number INFORMATION DISCLOSURE** 6/22/01 Filing Date 4 2002 STATEMENT BY APPLICANT Jeffry Weers et al **First Named Inventor** 1617 Art Unit TECH CENTER 1600/2900 (use as many sheets as necessary) K. Stiller **Examiner Name** Attorney Docket Number 0103.00 3 9 of Sheet

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
m	bo	US-5562608	10/07/1996	Sekins et al.			
1	bp	US-5770187		Hasebe et al.			
	bq	US-5766573		Purewal			
	br	US-5755218	05/26/1998	Johansson et al.			
	bs	US-5744123	04/29/1998	Akehurst e tal.			
	bt	US-5742352	04/28/1998	Rubsamen et al.			
	bu	US-5742350	04/28/1998	Gonda et al.			
	bv	US-5741522	04/21/1998	Violante et al			
	bw	US-5741478	04/21/1998	Osborne et al.			
	bx	US-5506203	04/09/1998	Backstrom et al.			
	by	US-5736124 .	04/07/1998	Akehurst et al.			
	bz	US-5735263	04/07/1998	Rubsamen et al.			
_	ca	US-5725871	03/10/1998	Illum			
	cb	US-5744166	04/28/1998	Illum			
	СС	US-5725841	03/10/1998	Duan et al.			
	cd	US-5724957		Rubsamen et al.			
	се	US-5720940		Purewal et al.			
	cd	US-5718222	02/17/1998	Lloyd et al.			
Ĺ	ce	US-5718921		Mathiowitz et al.			
	cf	US-5707352		Sekins et al.			

			FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1		n Patent Document mber ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Te
9	FM	WO	9524892	9/21/1995			
0,	FN	WO	9517195 /	6/29/1995			
	FO	wo	9515118 -	6/8/1995			
	FP	WO	9408627	4/28/1994			
	FQ	WO	9314172	7/22/1993			
	FR	wo	9311745	6/24/1993			
	FS	wo	9311744	6/24/1993			
	FT	wo	9214444	9/3/1992		**************************************	
	FU	wo	9112823	9/5/1991	· · ·	-	
V	FV	EP	0658101	6/21/1995			

1	Examiner	Date	/
l	Signature	Considered	12/02

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 09/888.311 **Application Number INFORMATION DISCLOSURE** 6/22/01 Filing Date STATEMENT BY APPLICANT Jeffry Weers et al. **First Named Inventor** 1617 Art Unit (use as many sheets as necessary) K. Stiller **Examiner Name** Attorney Docket Number 0103.00 4 of Sheet

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials*	ا	Document Number Number - Kind Code ² (if known)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1	cg	US-5695744	12/09/1997	Neale et al.	
	ce	US-5695743	12/09/1997	Purewal et al.	
	cf	US-5690954	11/25/1997	Illum	
	cg	US-5688782	11/18/1997	Neale et al.	
	ch	US-5683677	11/04/1997	Purewal et al.	•
	ci	US-5683676	11/04/1997	Akehurst et al.	
	cj	US-5681545	10/28/1997	Purewal et al.	
	ck	US-5676929	10/14/1997	Akehurst et al.	
	cl	US-5674473	10/07/1997	Purewal et al.	
	cm	US-5674472	<u> 10/07/1997</u>	Akehurst et al.	
-	cn	US-5674471	<u> 10/07/1997</u>	Akehurst et al.	
	со	US-5658549	08/19/1997	Akehurst et al.	
	ср	US-5653962	08/05/1997	Akehurst et al.	
	cq	US-5635161	06/03/1997	Adjei et al.	
	CT	US-5635159	06/03/1997	Fu Lu et al.	
	cs	US-5605674		Purewal et al.	
	ct	US-5580575		Unger et al.	
	cu	US-5569450	10/29/1996		
L	cv	US-5518731	05/21/1996		
	cw	US-5518709	05/21/1996	Sutton et al.	

		FOR	EIGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
muais	140.	Country Code3 -Number4 -Kind Code5 (if known)	MM-DD-YYYY	Applicant of Offed Bocament	or Relevant Figures Appear	T6
1/2	FW	EP 0616525	9/27/1995			
	FX	EP 0605578 ~	1/10/1996			
	FY	EP 0588897 —	2/28/1996			
	FZ	EP 0587790	1/3/1996			
	GA	EP 05562556 /	8/30/1995			
	GB	EP 0553298 -	11/17/1994			
	GC	EP 05365235	1/22/1997			
	GD	EP 0536204	4/6/1994			
	GE	EP 0513127 -	7/17/1995			
1	GF	EP 0499344 /	10/11/1995			

Examiner Date Signature Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

	6	P		
•	NUL	0 3	2002	055 J
B.	W.		Yr.	

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 09/888.311 **Application Number** INFORMATION DISCLOSURE 6/22/01 **Filing Date** STATEMENT BY APPLICANT Jeffry Weers et al. **First Named Inventor** 1617 Art Unit (use as many sheets as necessary) K. Stiller **Examiner Name** Attorney Docket Number 0103.00 5 of Sheet

<u></u>						<u> </u>
			U.S. PATI	ENT DOCUMENTS		g
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code 2 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	owo/zad
<	cx	US-5518998	05/21/1996	Backstrom et al.		4
10	су	US-5492688	02/20/1996	Byron et al.		\neg
UT	cz	US-5490498	02/13/1996	Faithfull et al.		\neg
	da	US-5474759	12/21/1995	Fassberg et al.		\neg
	db	US-5470885	11/28/1995	Furhman et al.		\neg
	dc	US-5437272	08/01/1995	Fuhrman		
	dd	US-5376359	12/27/1994	Johnson		\neg
	de	US-5348730		Greenleaf et al.		
	df	US-5299566	04/05/1994	Davis et al.		
	de	US-5284656	02/08/1994	Platz et al.		\Box
	df	US-5260306	11/09/1993	Boardman et al.		
	dg	US-5230884	07/27/1993	Evans et al.		
	dh	US-5225183	07/06/1993	Purewal et al.		
	di	US-5208226	05/04/1993	Palmer .		
	đj	US-5190029	03/02/1993	Byron et al.		
	dk	US-5182097	01/26/1993			
	dl	US-5173298	12/22/1992		,	\neg
	dm	US-5126123	06/30/1992			
	dn	US-5118494	06/02/1992	Schultz et al.		
	do	US-5011678	04/30/1991	Wang et al.		$\overline{}$

		5000				
	,	FORE	<u>IGN PATENT D</u>	OCUMENTS		
	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code3 -Number4 -Kind Code5 (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Τe
a	GG	EP 0493437 -	8/2/1995			
	GH	EP 0391896 -	3/2/1994		_	
	GI	EP 0372777	1/7/1993			
	GL	EP 0653205	5/17/1995			
	GK	EP 0656205 /	6/7/1995			
	GL	EP 0611567	8/24/1994			
	GM	EP 0274431	7/13/1988			
	GN	CA 2136704	5/28/1005			
	GO	EP 0655237	5/13/1995		-	
V	GP	CA 2036844	8/23/1991		*	

Examiner Date 20 Signature Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 09/888,311 **Application Number** INFORMATION DISCLOSURE 6/22/01 Filing Date STATEMENT BY APPLICANT Jeffry Weers et al First Named Inventor 1617 Art Unit (use as many sheets as necessary) K. Stiller Examiner Name Attorney Docket Number 0103.00 6 9 of Sheet

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known,		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	dр	US-4590206	-	Forrester et al.	
16	đq	US-5653961		McNally et al.	
0	dr	US-5770559	06/23/1998	Manning et al.	
	ds	US-5770222	06/23/1998	Unger et al.	
	dt	US-5747445	05/05/1998	Backstrom et al.	
	du	US-5830853	11/03/1998	Backstrom et al.	
	dv	US-5874063	02/23/1999	Briggner et al.	
	dw	US-5254330	10/19/1993	Ganderton et al.	
	dx	US-5891844	04/06/1999	Hafner	
	dy	US-4904479	04/06/1999	Illum	
	dz	US-5804212	09/08/1998	Illum	
	ea	US-5863554	01/26/1999	Illum	
	eb	US-5756104	05/26/1998	de Haan et al.	
	ec	US-5612053	03/18/1997	Baichwal	
	ed	US-5817293	10/06/1998	Akehurst et al.	
	ee	US-5308620	05/03/1994	Yen	
	ef	US-5616311	04/01/1997	Yen	
	eg	US-5547656	08/20/1996	Unger	
L	eh	US-5830430	11/03/1998		
	ci	US-5814607	09/29/1998	Patton	

			FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No. ¹		reign Patent Document -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
8	GQ	wo	9833487.	8/6/1998			
	GR	wo	9831346	7/23/1998			
V	GS	WO	9833480	8/6/1998			
	GT	WO	9830207	7/16/1998			
	GU	WO	9813031 🖊	4/2/1998			
	GV	wo	9500128	1/5/1995			
	GW	WO	9619199	6/27/1996			
	GX	WO	9829099	7/9/1998			
	GY	wo	. 9906026	2/11/1999			
	GZ	WO	9703649.	2/6/1997			

Examiner	1 ~ ~	Date	. /
Signature		1 1	12 / 43
Signature		Considered	16/16

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 7 of 9

C	mplete if Know	'n	
Application Number	09/888.311		
Filing Date	6/22/01		
First Named Inventor	Jeffry Weers e	et al.	
Art Unit			
Examiner Name	K. Stiller		
Attorney Docket Number	0103.00		
NT DOCUMENTS			
Name of Patentee or Applicant of Cited Docume	t Relevant P	umns, Lines, Where assages or Relevant ures Appear	

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials*	4	Document Number Number - Kind Code ² (if known		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
4	ej	US-5855913	01/05/1999	Hanes et al.	
11	ek	US-5874064	02/23/1999	Edwards et al.	
V	el	US-5856367	01/05/1999	Barrows et al.	
	em	US-5811406	09/22/1998	Szoka et al.	
	en	US-5858784	01/12/1999	Debs et al.	
	eo	US-5820883	10/13/1998	Tice et al.	
	ер	US-3014844	12/26/1961	Thiel et al.	
	eq	US-4818542	04/04/1989	DeLuca et al.	
	ег	US-5069936	12/03/1991	Yen	
	ge	US-5989028	4/27/1999	Jensen et al.	
	gf	US-5654007	8/5/1997	Johnson et al.	
	gg	US-5667809	9/16/1997	Trevino et al.	
(gh	US-5770585	6/23/1998	Kaufman et al.	
1	gi	US-5994318	11/30/1999	Mannino	
		US-			
V		US-			
	<u> </u>	US-			

		FOR	EIGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code 3 - Number 4 - Kind Code 5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
(HA	WO 9218164 -	10/29/1992			
1	НВ	WO 9740819	11/6/1997			
	HC	WO 9111173	8/8/1991			
	HD	WO 9200107	1/9/1992			
	HE	WO 9632149	10/17/1996		· · · · · · · · · · · · · · · · · · ·	
	HF	WO 9640068	12/19/1996	7 · · · · · · · · · · · · · · · · · · ·		
	FG	WO 9741833 -	11/13/1997			
	FH	WO 9816205	4/23/1998			
	FI	WO 9829098 /	7/9/1998			
0	FJ	WO 9829140 /	7/9/1998			

Examiner Signature Date Considered 12/12

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitut	e for form 1449A/PT	ю		Complete if Known			
		. Dic	OI OOUDE	Application Number	09/888.311		
INFC	PRIMATION	DIS	SCLOSURE	Filing Date	6/22/01		
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Jeffry Weers et al.		
				Art Unit	1617		
 	(use as many she	eets as	necessary)	Examiner Name	K. Stiller	·	
Sheet 8 of 9			· 9	Attorney Docket Number	0103.00		

		U.S. PATE	NT DOCUMENTS	
Examiner Initials*	Cite No. 1 Number - Kind Code 2 (if knd	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
!	US-			
:	US-			
	US-	,		
	US-			· · · · · · · · · · · · · · · · · · ·

			FORE	IGN PATENT D	OCUMENTS		
Examiner	Cite		oreign Patent Document		Name of Patentee or	Pages, Columns, Lines,	
	No.1	Country Code	3 -Number4 -Kind Code5 (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Le
4	FK	wo	9505194	2/23/1995			
	FL	wo	9829097 /	7/9/1998			
0	FM	wo	9800111	1/8/1998			
	FN	WO	9104011	4/4/1991		··· · · · · · · · · · · · · · · · ·	
	FO	EP	0539522	12/20/1998			
	FP	wo	9609814	4/1996			
	FQ	WO	9116882	11/14/991			
	FR	WO	9932083 /	7/1/1999			
	FS	EP	0655237	5/31/1995		-	
9/	FT	wo	9726863	7/31/1999		· · · · · · · · · · · · · · · · · · ·	

		1		
Examiner	. ^ _	Date	l /	′
Signature				01
Signature		Considered		



^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

	OPE
	JUN 0 3 2002 85
HE	C TRODEMASS
_1A:	CADEMACS.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1996, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			·	Complete if Known			
INICO		N DIOC	N OOUDE	Application Number	09/888311		
INFORMATION DISCLOSURE				Filing Date	6/22/01	- 1	
STAT	EMENT	BY AP	PLICANT	First Named Inventor	Jeffry Weers et al.		
				Art Unit	1617		
· (L	ise as many s	sheets as ne	cessary)	Examiner Name	K. Stiller		
Sheet	9	of	9	Attorney Docket Number	0103.00		

		U.S. PATE	NT DOCUMENTS	
Examiner (Initials*	Cite No. 1 Number - Kind Code 2 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US-			

		FORE	IGN PATENT D	OCUMENTS	•	
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code 3 - Number 4 - Kind Code 5 (il known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
4	FU	EP 0372777	6/13/1990			
7	FV	WO 9807414.	2/26/1998		-	
	FW	RU 93008753		Jan i		
	FX	'RU 91263780				
	FY	RU 92025196			···	
Ω	FZ	WO 9218164	10/19/1992			
1	GA	WO 9528944	11/2/1995			
	GB	WO 9637399	3/14/1996			
N	GC	WO 9640277	12/19/1996			
	!					

Examiner Signature	Date	17/67
Signature	Considered	1400

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

/	Ó	P	188
	JUN	0 3 200	MCER
PATE	& Trial	- 9 ZUUZ	6
k Red	G TRA	DEMARK	5 no ne

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			Complete if Known			
MEA	3888 7 16	DIO		Application Number	09/	888.311
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				I ————————————————————————————————————		2/01
				First Named Inventor	We	ers et al.
(use as many sheets as necessary)			Art Unit	161	7	
			Examiner Name	K. 9	Stiller	
Sheet	1	of	1	Attorney Docket Number	010	03.00
			U.S. PATI	ENT DOCUMENTS		
xaminer Cite	Document	Number	Publication Date	Name of Patentee or		Pages, Columns, Lines, Where

	<u> </u>	U.S. PATE	NT DOCUMENTS	
Examiner Initials*	Cite No. 1 Number - Kind Code 2 (if)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	US-			
:	US-			
	US-	·		
	US-			

		FORE	IGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code 3 - Number 4 - Kind Code 5 (if known)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
9	gk	wo 9916419 /	4/8/1999			H
1	gl	wo 0113892	3/1/2001			
-						
						├
						┢
						\vdash
						<u> </u>

			y	
Examiner	Γ Λ	Data		1
		Date	i .	/ 50
Signature		Considered	10	100
		Octionacion		<u></u>

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction action 395, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

ubstitute for form 1449B/PTO					Complete if Known			•
					Application Number	09/888.311		컮
NFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)					Filing Date	6/22/01 Jeffry Weers et al.		Þ
					First Named Inventor			出
					Group Art Unit	1617		M
					Examiner Name	K. Stiller		E
Sheet		1	of	1	Attorney Docket Number	0103.00		宏
		ОТН	R PRIC	OR ART NON PA	ATENT LITERATURE DO	CUMENTS		600
Examiner Initials* Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ²)/2900		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²				
J	1	ABDELLAZIZ BEN-JEBRIA ET AL., "Large Porous Particles for Sustained Protection from Carbachol-Induced Brnchoconstriction in Guinea Pigs," Pharm Res, Vol. 16 (No. 4), p. 555-561,					
	2	ZARIF ET AL., "Amphotericin B Cochleates as a Novel Oral Delivery System," International Symposium, p. 964-965, —					
	3	HAUSER ET AL., "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes," Biochem., p. 34-41, -					
V							
	,						
		,					
<u></u>							
Examine: Signature		Date Considered 12/0)					

Examiner		_	Date	10	/
Signature			 Considered	17 1	02

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.